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UTILITY PATENT APPLICATION TRANSMITTAL <small>(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))</small>	Attorney Docket No.	INS-31061-A
	First Inventor or Application Identifier	Alan R. Hirsch
	Title	See 1 in Addendum
	Express Mail Label No.	EL587909762US

APPLICATION ELEMENTS <small>See MPEP chapter 600 concerning utility patent application contents</small>	ADDRESS TO: Assistant Commissioner for Patents Box Patent Application Washington, DC 20231
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1. <input checked="" type="checkbox"/> * Fee Transmittal Form (e.g., PTO/SB/17) <small>(Submit an original and a duplicate for fee processing)</small>	5. <input type="checkbox"/> Microfiche Computer Program (Appendix)
2. <input checked="" type="checkbox"/> Specification [Total Pages 24] <small>(preferred arrangement set forth below)</small> <ul style="list-style-type: none">- Descriptive title of the Invention- Cross References to Related Applications- Statement Regarding Fed sponsored R & D- Reference to Microfiche Appendix- Background of the Invention- Brief Summary of the Invention- Brief Description of the Drawings (if filed)- Detailed Description- Claim(s)- Abstract of the Disclosure	6. Nucleotide and/or Amino Acid Sequence Submission <small>(if applicable, all necessary)</small> <ul style="list-style-type: none">a. <input type="checkbox"/> Computer Readable Copyb. <input type="checkbox"/> Paper Copy (identical to computer copy)c. <input type="checkbox"/> Statement verifying identity of above copies

3. <input type="checkbox"/> Drawing(s) (35 U.S.C. 113) [Total Sheets 1]	ACCOMPANYING APPLICATION PARTS 7. <input type="checkbox"/> Assignment Papers (cover sheet & document(s)) 8. <input type="checkbox"/> 37 C.F.R. § 3.73(b) Statement of Power of Attorney <small>(when there is an assignee)</small> 9. <input type="checkbox"/> English Translation Document (if applicable) 10. <input checked="" type="checkbox"/> Information Disclosure Statement (IDS)/PTO-1449 <input checked="" type="checkbox"/> Copies of IDS Citations 11. <input checked="" type="checkbox"/> Preliminary Amendment 12. <input checked="" type="checkbox"/> Return Receipt Postcard (MPEP 503) <small>(Should be specifically itemized)</small> 13. <input checked="" type="checkbox"/> * Small Entity Statement(s) <input checked="" type="checkbox"/> Statement filed in prior application <small>(PTO/SB/09-12)</small> Status still proper and desired 14. <input type="checkbox"/> Certified Copy of Priority Document(s) <small>(if foreign priority is claimed)</small> 15. <input type="checkbox"/> Other:	
4. Oath or Declaration [Total Pages 3] <ul style="list-style-type: none">a. <input type="checkbox"/> Newly executed (original or copy)b. <input checked="" type="checkbox"/> Copy from a prior application (37 C.F.R. § 1.63(d)) <small>(for continuation/divisional with Box 16 completed)</small><ul style="list-style-type: none"><input type="checkbox"/> DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).		
* NOTE FOR ITEMS 1 & 13 IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).		
16. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment: <input type="checkbox"/> Continuation <input checked="" type="checkbox"/> Divisional <input type="checkbox"/> Continuation-in-part (CIP) of prior application No. 09/211,507 <small>Prior application information: Examiner C. Tate Group / Art Unit. 3736</small>		
For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.		

17. CORRESPONDENCE ADDRESS	
<input checked="" type="checkbox"/> Customer Number or Bar Code Label 022202 <small>(Insert Customer No. or Attach bar code label here)</small>	or <input type="checkbox"/> Correspondence address below

PATENT AND TRADEMARK OFFICE			
Name			
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Name (Print/Type)	Kristine M. Strodthoff	Registration No. (Attorney/Agent)	34259
Signature	<i>Kristine M. Strodthoff</i>	Date	07 NOV 2000

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1. Use of Odorants to Alter Vaginal Blood Flow, and Article of Manufacture Therefor

1. Use of Odorants to Alter Vaginal Blood Flow, and Article of Manufacture Therefor

FEE TRANSMITTAL

for FY 2000

Patent fees are subject to annual revision
Small Entity payments must be supported by a small entity statement,
otherwise large entity fees must be paid See Forms PTO/SB/09-12
See 37 CFR §§ 1.27 and 1.28

TOTAL AMOUNT OF PAYMENT (\$400.00)

Complete if Known

Application Number	
Filing Date	
First Named Inventor	Alan R. Hirsch
Examiner Name	C. Tate
Group / Art Unit	3736
Attorney Docket No.	INS-31061-A

METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayments to

Deposit Account Number

Deposit Account Name

☐ Charge Any Additional Fee Required
Under 37 CFR §§ 1.16 and 1.17

2. ☒ **Payment Enclosed:**
☒ Check ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
101 690	201 345	Utility filing fee	355.00
106 310	206 155	Design filing fee	
107 480	207 240	Plant filing fee	
108 690	208 345	Reissue filing fee	
114 150	214 75	Provisional filing fee	

SUBTOTAL (1) (\$355.00)

2. EXTRA CLAIM FEES

Total Claims	Extra Claims	Fee from below	Fee Paid
25	-20** = 5	9	45
Independent Claims	3	-3** = 0	0
Multiple Dependent			0

**or number previously paid, if greater; For Reissues, see below

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
103 18	203 9	Claims in excess of 20
102 39	202 39	Independent claims in excess of 3
104 260	204 130	Multiple dependent claim, if not paid
109 78	209 39	** Reissue independent claims over original patent
110 18	210 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$45.00)

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
105 130	205 65	Surcharge - late filing fee or oath	0.00
127 50	227 25	Surcharge - late provisional filing fee or cover sheet	0.00
139 130	139 130	Non-English specification	0.00
147 2,520	147 2,520	For filing a request for reexamination	0.00
112 920*	112 920*	Requesting publication of SIR prior to Examiner action	0.00
113 1,840*	113 1,840*	Requesting publication of SIR after Examiner action	0.00
115 110	215 55	Extension for reply within first month	0.00
116 380	216 190	Extension for reply within second month	0.00
117 870	217 435	Extension for reply within third month	0.00
118 1,360	218 680	Extension for reply within fourth month	0.00
128 1,850	228 925	Extension for reply within fifth month	0.00
119 300	219 150	Notice of Appeal	0.00
120 300	220 150	Filing a brief in support of an appeal	0.00
121 260	221 130	Request for oral hearing	0.00
138 1,510	138 1,510	Petition to institute a public use proceeding	0.00
140 110	240 55	Petition to revive - unavoidable	0.00
141 1,210	241 605	Petition to revive - unintentional	0.00
142 1,210	242 605	Utility issue fee (or reissue)	0.00
143 430	243 215	Design issue fee	0.00
144 580	244 290	Plant issue fee	0.00
122 130	122 130	Petitions to the Commissioner	0.00
123 50	123 50	Petitions related to provisional applications	0.00
126 240	126 240	Submission of Information Disclosure Stmt	0.00
581 40	581 40	Recording each patent assignment per property (times number of properties)	0.00
146 690	246 345	Filing a submission after final rejection (37 CFR § 1.129(a))	0.00
149 690	249 345	For each additional invention to be examined (37 CFR § 1.129(b))	0.00
Other fee (specify) _____			0.00
Other fee (specify) _____			0.00

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$0.00)

SUBMITTED BY

Name (Print/Type)	Kristine M. Strodthoff	Registration No (Attorney/Agent)	34259	Telephone	414-273-2100
Signature	<i>Kristine M Strodthoff</i>	Date	07 Nov 2000		

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Attorney's Docket No.: 054012-0009

PATENT

Applicant: Alan R. Hirsch

Serial or Patent No.: 09/211,507

Filed: December 14, 1998

For: USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR

**VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS
37 CFR 1.9(f) and 1.27(b))-INDEPENDENT INVENTOR**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under Section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled: USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR, described in U.S. patent application Serial No. 09/211,507, filed December 14, 1998.

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an obligation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ [X] no such person, concern, or organization
☐ [] persons, concerns or organizations listed below*

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities. (37 CFR 1.27).

FULL NAME: _____

ADDRESS: _____

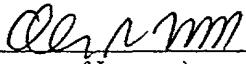
☐ [] INDIVIDUAL ☐ [] SMALL BUSINESS CONCERN ☐ [] NONPROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Alan R. Hirsch
(Name of inventor)

845 N. MELBURN AVE
(Address)


(Signature of Inventor)

Date: 2/9/99

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Alan R. Hirsch

Serial No. : Unknown (Divisional of USSN 09/211,507)

Filing Date : Herewith

For : USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW,
AND ARTICLE OF MANUFACTURE THEREFOR

Attorney Docket No. : INS-31061-A

CERTIFICATION UNDER 37 CFR 1.8(a) and 1.10

I hereby certify that, on the date shown below, this correspondence is being:

Mailing

- ☒ deposited with the United States Postal Service in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231, Box Patent Application

37 CFR 1.8(a)

37 CFR 1.10

- ☐ with sufficient postage as first class mail ☒ As "Express Mail Post Office to Addressee" Mailing Label No. EL587909762US

Transmission

- ☐ transmitted by facsimile to Fax No _____ addressed to Examiner _____ at the Patent and Trademark Office.

Date: 11-7-00

Jan R. Mark

Assistant Commissioner for Patents
BOX PATENT APPLICATION
Washington, D.C. 20231

COMMUNICATION AND PRELIMINARY AMENDMENT

Sir:

This application is a divisional of U.S. Serial No. 09/211,507. **Prior to calculating the filing fee, please cancel Claims 2-23.**

Preliminary Amendment

Prior to substantive examination, Applicant requests the following amendments be made in this application.

IN THE CLAIMS

Claims 2-23 have been cancelled in the filing of this divisional application, Please cancel Claim 1, and add new Claims 24- 48, as follows.

24. An article of manufacture, comprising, packaged together:
a unit dosage amount of an odorant packaged in a container, to alter vaginal blood flow when inhaled by a female individual; and
instructions for administering the odorant to alter vaginal blood flow.
25. The article of manufacture according to Claim 24, further comprising at least one of the following:
a device for measuring vaginal blood flow of the female individual; and
means for testing olfactory ability in the female individual.
26. The article of manufacture of Claim 24, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.
27. The article of manufacture of Claim 24, wherein the concentration of the odorant is at about 25-55 decismel units.
28. The article of manufacture of Claim 24, wherein the odorant is packaged within a delivery device selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.
29. The article of manufacture of Claim 24, wherein the odorant is in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.

30. The article of manufacture of Claim 24, wherein the odorant is in the form of a cream or a cologne.

31. The article of manufacture of Claim 24, wherein the odorant is in a liquid form contained in a dispenser.

32. The article of manufacture of Claim 31, wherein the dispenser has a tip impregnated with the odorant.

33. The article of manufacture of Claim 32, wherein the dispenser contains the odorant absorbed to a wicking material.

34. The article of manufacture of Claim 24, wherein the odorant is selected from the group consisting of a baby powder odorant, a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, a floral-aldehydic perfume odorant, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants.

35. The article of manufacture of Claim 24, wherein the odorant comprises a mixture of a licorice-based and cucumber odorant.

36. The article of manufacture of Claim 24, wherein the unit dosage amount of the odorant is effective to increase vaginal blood flow of the female individual by about 10-30%.

37. The article of manufacture of Claim 36, wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a baby powder odorant, a mixture of a lavender and pumpkin pie odorant, and a mixture of a baby powder and chocolate odorant.

38. The article of manufacture of Claim 24, wherein the unit dosage amount of the odorant is to decrease vaginal blood flow of the female individual by about 10-20%.

39. The article of manufacture of Claim 38, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant, a mixture of licorice-based and cucumber odorants, and a floral-aldehydic perfume odorants.

40. The article of manufacture of Claim 38, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant.

41. An article of manufacture, comprising, packaged together:
a unit dosage amount of an odorant packaged in a container, to increase vaginal blood flow when inhaled by a female individual; and
instructions for administering the odorant to increase vaginal blood flow.

42. The article of manufacture of Claim 41, wherein the unit dosage amount of the odorant is effective to increase vaginal blood flow of the female individual by about 10-30%.

43. The article of manufacture of Claim 41, wherein the odorant is selected from the group consisting of a mixture of a licorice-based and cucumber odorant, a baby powder odorant, a mixture of a lavender and pumpkin pie odorant, and a mixture of a baby powder and chocolate odorant.

44. The article of manufacture of Claim 41, wherein the odorant comprises a mixture of a licorice-based and cucumber odorant.

45. An article of manufacture, comprising, packaged together:
a unit dosage amount of an odorant packaged in a container, to decrease vaginal blood flow when inhaled by a female individual; and
instructions for administering the odorant to decrease vaginal blood flow.

46. The article of manufacture of Claim 45, wherein the unit dosage amount of the odorant is to decrease vaginal blood flow of the female individual by about 10-20%.

47. The article of manufacture of Claim 45, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant, a mixture of licorice-based and cucumber odorants, and a floral-aldehydic perfume odorants.

48. The article of manufacture of Claim 45, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant.

IN THE SPECIFICATION

Please amend the specification as follows.

At page 1, line 5 (Cross-Reference to Related Applications), after “This application” insert —is a divisional of U.S. Patent Application Serial No. 09/211,507, filed December 14, 1998, and--.

REMARKS

Consideration of the newly added and pending Claims 24-48 is requested. Support for the claims is in the original claims as filed, and in the specification at page 7, lines 17-18 (unit dosage amount).

It is respectfully submitted that the claims are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is urged to telephone the undersigned attorney if any questions should arise.

Respectfully submitted,



Kristine M. Strodthoff
Registration No. 34,259

Dated: November 7, 2000

P.O. ADDRESS:
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Customer No. 022202

633416v1

**USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW,
AND ARTICLE OF MANUFACTURE THEREFOR**

CROSS-REFERENCE TO RELATED APPLICATIONS

5 This application claims the benefit of U.S. Provisional Application Serial
No. 60/069,460, filed December 15, 1997.

BACKGROUND OF THE INVENTION

10 Various researchers have focused attention on odors and their connection with
sexuality. Almost a hundred years ago, Sigmund Freud was concerned that if the sense
of smell was not repressed, men -- but not necessarily women -- would walk around
sexually excited all the time. Freud also linked odor with the Oedipal conflict when he
said that during a boy's development, he learns to recognize the odor of both parents,
15 and eventually he comes to dislike the father's odors and have positive associations with
the mother's odors. Although Freud also spoke of the Electra Complex, a
corresponding development conflict in girls, he made no mention of the significance of
the parent's odors in female psychological maturation.

20 In men, an erection occurs when increased blood flow to the penis causes
spongelike chambers to become engorged as the blood vessels of the penis expand. In
women, arousal causes increased blood flow to the vagina, which expands the vaginal
tissues and stimulates the release of lubricating fluids along the walls of the vagina.
The clitoris becomes engorged during the arousal phase because of increased blood
flow to the region.

25 Sexual dissatisfaction is common among married couples in our society, and
arousal disorders are a very common form of sexual dysfunction. In the early 1950s, a
survey by sex researcher Alfred Kinsey found that 10 percent of married women never
experienced coital orgasm. (Kinsey et al., *Sexual Behavior in the Human Female*,
Philadelphia: W.B. Saunders (1953)). In 1956, a British study of 3,705 women

reported that 10 percent of women rarely experienced orgasm and another 5 percent never experienced orgasm during intercourse. (E. Chesser, *The Sexual Marital and Family Relationships of the English Woman*, London: Hutchinson's Medical Publications (1956)). In the 1970s, a study in the United States reported 17 percent of women seen at a gynecologic clinic stated that they had difficulty achieving orgasm with a partner, and 6 percent had never experienced orgasm with a partner. (E. Frank et al., *N. Engl. J. Medicine* 299:111 (July 20, 1978)).

Research into olfactory-related sexual behavior has been documented in laboratory animals. Pheromones, which are chemical substances produced by an organism for purposes of chemo-communication with another of the same species, have been documented in many animals. Pheromones are not consciously recognized by the brain but influence hormone production, and sexual attraction, drive and even behavior. Although pheromones exist throughout the animal kingdom, it is not known for certain that human pheromones exist. One postulated human pheromone system concerns menstruation. It has been observed that women who live in close contact with one another menstruate together. Another system involves the steroid androsterone which has been named as a pheromone that is secreted from the apocrine glands located in the underarm area and around the genital organs. Androsterone has been found to have an attractant effect on women and an aversive effect on men. Alternate theories suggest that what we call potential pheromones are simply odors associated with sex, and human response to them is conditioned.

There has been other research into the olfactory-sexual link. When the olfactory bulb was lesioned in hamsters, it caused an impaired sex drive. An olfactory-sexual connection has also been observed in laboratory animals that were castrated. The castration led to both impaired sexual drive and olfactory functioning. Ovariectomies led to both impaired sexual functioning and reduced olfactory ability. Lesions of the olfactory bulb or of the nasal cartilage alone, caused both an olfactory deficit and a malformation of the developing animal's sex organs. These studies indicate a link between olfaction, olfactory organs and sexual functioning.

blood flow, and a kit, or article of manufacture, containing a odorant and instructions for its use in altering vaginal blood flow.

5

DETAILED DESCRIPTION OF THE INVENTION

In one embodiment of the invention, the odorant can be administered in an amount sufficient to increase vaginal blood flow of the female individual. By increasing vaginal blood flow, the female individual will experience increased or enhanced sexual arousal. Examples of odorants and odorant mixture that can be administered to increase vaginal blood flow by about 10-30%, include a baby powder odorant, a mixture of licorice-based odorant and banana nut bread odorant, a mixture of a licorice-based odorant and cucumber odorant, a floral-aldehydic perfume fragrance such as Chanel No. 5 and White Linen, a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants. Examples of licorice-based odorants include a black licorice odorant, and Good N' Plenty® (licorice and anise) odorant. Such odorants are commercially available, for example, from International Flavors and Fragrances, Inc. (IFF, New York, NY), Energy Essentials, AromaTech, Inc. (Somerville, NJ), Florasynth, Inc. (Teterboro, NJ), and as essential oils. Such individual odorants and odorant mixtures have been found to be particularly useful in increasing vaginal blood flow in female individuals who are highly aroused by masturbation.

According to the invention, odorants can also be administered to decrease vaginal blood flow of a female individual. With a reduction in vaginal blood flow, the female individual experiences an inhibited or reduced level of sexual arousal. Examples of odorants and odorant mixture that can be administered to decrease vaginal blood flow by about 10-20% include a licorice-based odorant alone, a mixture of a licorice-based odorant and cucumber odorant, a cologne such as Old Spice®, a floral-aldehydic perfume fragrance such as Chanel No. 5 and White Linen, a charcoal barbecue meat odorant, and a cherry odorant. Such odorants and odorant mixtures have been found to be

particularly useful in reducing vaginal blood flow in female individuals who are minimally or not highly sexually aroused by masturbation or manual manipulation of the female genitals.

5 In the use of odorants to stimulate or decrease vaginal flow, it is preferred that the subject individual is presented with the odorant at a suprathreshold concentration (e.g., about 25-55 decismel units), but not irritative level, and inhales the odorant for about 1-3 minutes.

10 An odorant is presented at a suprathreshold level when the decismel level or concentration of the odorant is beyond that needed to be detected by a normosmic individual. At its irritative level, the odorant quantity is so high and intense that the odorant stimulates predominantly the trigeminal nerve (for pain) rather than the olfactory nerve and, hence, is perceived as noxious or painful. The irritation threshold of the patient is the lowest concentration of the substance that causes immediate stinging or burning sensations in the nose, or stinging or lacrimation of the eye. See, J.F. Gent,
15 in *Clinical Measurement of Taste and Smell*, pages 107-166, H.L. Meiselman et al. (eds.), 602 pp., MacMillan, NY (1986); R.L. Doty et al., *Ann. Neurol.* 25: 166-171 (1989); E. Koss et al., *Neurology* 38: 1228-1232 (1988); and R. Doty, *The Smell Identification Test: Administration Manual* 1983: 13-14, Philadelphia: Sensonics, Inc. (1983).

20 Preferably, prior to the administration of the odorant, the individual undergoes olfactory testing according to a test such as the University of Pennsylvania Smell Identification Test (UPSIT), a 40-question forced-choice, scratch-and-sniff identification test, and the Chicago Smell Test, a 3-item detection and identification test (R. Doty, *The Smell Identification Test: Administration Manual* 1983: 13-14,
25 Philadelphia: Sensonics, Inc. (1983); A.R. Hirsch et al., *Chemical Senses* 18(5): 570-571 (1993); A.R. Hirsch et al., *Chemical Senses* 17(5): 643 (1992)). The individual can also be evaluated for olfactory capacity (e.g. loss of smell) according to an olfactory threshold test as known and used in the art. Such a test provides a precise magnitude of loss of smell and classifies the individual as normosmic, hyposmic or

anosmic, which is useful in assessing the effectiveness of a particular odorant and/or the required concentration of the odorant to provide a suprathreshold level to effectively reduce migrainous symptoms. According to that test, an odorant substance such as butyl alcohol, phenyl ethyl alcohol, or pyridine, is combined in an odorless liquid medium to provide a series of dilutions, or binary steps, of the odorant. For each successive binary step up the dilution scale, the odorant is present, for example, at one half the concentration of the preceding step. The highest concentration of the odorant usually provides the substance at an irritant level. The individual is presented with the series of dilutions in ascending order, and is asked to compare each dilution step to at least one control stimulus, such as odorless propylene glycol.

Ranges of the average normal threshold for various odorant substances can be found in the art, for example, Amoore and O'Neill, "Proposal for Unifying Scale to Express Olfactory Thresholds and Odor Levels: The "Decismel Scale", in *Proceedings of the 1988 Air Pollution control Association Annual Meeting*, Paper No. 78.5 (21 pp.), Air and Waste Management Association, Pittsburgh, PA (1988); Amoore and Haotata, "Odor as an Aid to Chemical Safety: Odor Thresholds Compared with Threshold Limit Values and Volatiles for 214 Industrial Chemicals in Air and Water Dilution," *J. Appl. Toxicology* 3(6):272-290 (1983).

In the art, a "normosmic" individual is one who can detect the odor of a substance without irritant sensations when the odorant is presented within the range of its average normal threshold. A "hyposmic" or "microsmic" individual has reduced capacity of the olfactory nerve being able to detect an odorant substance by its odor at a concentration, or decismel level, above that of a normosmic individual yet below its irritant concentration level. An "anosmic" individual is one who has essentially no olfactory nerve capacity being unable to detect the odor of the odorant substance, but has trigeminal nerve function, being able to detect an odorant substance by means of irritant, tingling sensations when it is present at an irritant concentration. A patient who is able to detect pyridine vapor by means of irritant, tingling sensations caused by stimulation of the trigeminal nerve, but who cannot distinguish a pyridine odor at a

lower concentration without such sensation, is considered to be anosmic having no olfactory nerve sensitivity.

The odorant substance is dispensed to a subject in a form that provides a vaporous emission for inhalation. The odorant substance can be administered in a liquid or solid form contained in a capped vessel, by opening a blister pack or scratch-and-sniff odor patch containing microcapsules of the odorant, as a spray from an aerosol or non-aerosol pump-type spray device, by means of a scented cloth, as a nasal spray, as a cologne or a cream, from a pen-like dispenser containing a liquid form of the odorant, and the like. Such a pen-type dispenser can be composed of a dispenser that has a tip impregnated with the odorant; the dispenser preferably contains a liquid form of the odorant, optionally adsorbed to a wicking material. It is preferred that the odorant is provided in a portable dispenser that is easily transportable and readily accessible by a person in need of relief, for example, a blister pack, booklet of scratch-and-sniff odor patches, pen-type dispenser, and the like.

The odorant substance can be packaged as part of a kit in association with a container such as a vial, jar, pouch, bottle, cloth, aerosolizer, blister pack, and the like, that holds an effective amount, or unit dosage amount, of the odorant to increase/decrease vaginal flow when administered to a female individual; and written or other form of instructions (e.g., video or cassette tape) of the use of the odorant to alter vaginal flow. The kit can also include a substance and instructions for testing olfactory capacity for the presence and/or identity of an odorant, and/or olfactory threshold. The various parts of the kit can be packaged separately and contained within a box or other packaging material.

Odorants can be screened for their effectiveness in altering vaginal blood flow by administering the odorant by inhalation in an amount and for a time period effective to alter vaginal blood flow. The effect of an odorant and/or odorant mixture can be assessed and measured objectively by administering a test to measure initial vaginal blood flow, and then re-testing the subject after being given the odorant. The effectiveness of the odorant on the subject to increase or decrease vaginal flow can be

assessed by comparing the amount of vaginal blood flow before and after inhaling the odorant.

The effect of an odorant or mixture of odorants can also be assessed subjectively by interviewing and questioning the female individual as to the effectiveness of the
5 odorant in increasing or decreasing the level of their sexual arousal (e.g., whether they are experiencing an increase or decrease in sexual stimulation) before and after inhaling the odorant substance.

The therapeutic implications of the present method are many. Individual females can benefit by inhaling certain odorants that will enhance or decrease their
10 sexual arousal, and hence, help treat sexual arousal disorders. The use of odorants in increasing or decreasing vaginal blood flow provides a useful therapy that is also easy to administer for those who are in need of enhanced or repressed sexual arousal. The invention will be further described by reference to the following detailed example. This example is not meant to limit the scope of the invention that has been set forth in
15 the foregoing description. Variations within the concepts of the invention are apparent to those skilled in the art. The disclosures of the cited references throughout the application are incorporated by reference herein.

20 EXAMPLE

A study was conducted to assess the effect of odorants on vaginal blood flow, a measure of the level of female sexual arousal and excitation. Thirty adult pre-menopausal, perialivatory women volunteered for this IRB approved study. Subjects were 18-40 years old, were not on any prescription or non-prescription
25 medication including oral contraceptives, were literate in English, non-lactating, not actively attempting pregnancy, not smoking for at least one year, consumed less than one drink of alcohol per day, not using cocaine or other illegal drug, and had no genital sexual stimulation by self or their partner for 48 hours prior to the study session. All scored normosmic on the University of Pennsylvania Smell Identification Test.

The subjects had no diseases known to induce autonomic disorders or chemosensory disorders, and were not on medications that produce chemosensory disorders.

5 **Methods.** After being positioned on the examination table, a vaginal process
graphic recording device was applied. The device was a sterile monitoring gauge, a
photophlethysmograph, similar in shape to a tampon, which was placed into the vagina.
The monitoring device measured pulse pressure which indicates change in blood flow to
the vagina. The gauge was hooked up to a computer and changes in pulse strength
10 were recorded on a continual basis.

A three minute period was allowed for acclimation to the experimental
environment or a longer duration was allowed until stable baseline measurements were
obtained (which measures vaginal bloodflow). A surgical mask untreated with any
added odor, was applied over the subject's mouth and nose for one (1) minute. During
15 this time, vaginal blood flow was recorded. After the one-minute measurement was
taken, the women were asked if the odor was familiar, if they could identify it, and if
they liked it or disliked it. Following this, the mask was removed for a three (3)
minute, no odor "washout" period during which blood flow was measured when no
mask was in place. This was to eliminate the effect of the odor -- positive or negative -
20 - so that blood flow returned to baseline. In a double-blind, randomized fashion in
which neither the subjects nor the test administrators knew which scents were being
tested at any given time during the study, ten (10) surgical masks that had been
pre-impregnated with different individual odors or odor mixtures were applied in a
similar fashion as in the initial blank mask and recorded to obtain in a similar fashion to
25 the original blank mask. After this, another blank mask and recordings were obtained,
with the initial and final blank mask used as markers of baseline.

Bloodflow was determined with the farral vaginal photophlethysmograph, and
computer-assisted therapy device as per published protocol. All odors were
FDA/GRAS approved and impregnated on molded paper 3M surgical masks at

suprathreshold, non-trigeminal levels as determined by an independent panel of the Smell and Taste Treatment Research Foundation. Statistical analysis was performed independently by the University of Illinois, School of Public Health. Statistical significance was timed by P value less than or equal to 0.05. Data was analyzed using
5 non-parametric tests of Signed Rank Test, Wilcoxin Rank Sum Test, and Spearman's Rank Correlation Coefficient. (T. Colton, *Statistics in Medicine*, Little Brown & Co., Boston, MA (1974); E.L. Lehmann, *Nonparametrics: Statistical Methods Based on Ranks*, Holden-Day, New York, NY (1975)).

Each woman was also given a series of tests of olfactory ability. Subjects
10 underwent standardized olfactory testing with the University of Pennsylvania Smell Identification Tests (UPSIT), a 40-question forced choice scratch-and-sniff test in which the person is given four choices for each question and that has been normalized at age and sex. For example, in one question, an odor is presented, and the individual is asked if the odor is pizza, motor oil, peanuts, or lilac. Each subject was also given an
15 odor threshold test, the Pyridine Olfactory Threshold test, a forced-choice test during which bottles containing various concentrations of pyridine, a chemical whose odor resembles scallops. This test evaluates the concentration of the odor that must be present before it is detectable. With this group of tests, olfactory acuity could be established, and those subjects who had a normal sense of smell and those with lesser
20 or no ability to smell.

Subjects also underwent a series of questionnaires regarding demographic data, sexual history data, sexual history and olfactory preference. These included a vaginal bloodflow study questionnaire which queried regarding use of cologne and food
hedonics, as well as sexual conduct and behavior. Subjects were questioned as to
25 favorite colognes and whether they or their sexual partner wore a perfume or cologne on a regular basis, favorite and least favorite food, number of sexual partners and encounters in the previous thirty days, sexual preference, and odors that recalled childhood.

The subjects were also questioned about orgasmic functioning, including frequency in the last thirty days and over the previous six months. Through these questions, the number of women who experienced orgasm but did so infrequently, and a group who were multiorgasmic were determined.

5 The subjects also completed the Sexual Arousal Ability Inventory, a standardized test of accessing ease of arousability on a negative 1 to 5 scale (Hoon, E.F., Hoon, P.W., and Wincze, J.P., The SAI: "An Inventory for the Measurement of Female Sexual Arousability," *Arch. Sex. Behav.* 5:291-300 (1976)), and the Sexual Arousal Ability Inventory which accesses a negative 1 to 5 scale degree of anxiety
10 induced by a variety of sexual activity (Chambles, D.L., and J.L. Lifshitz, "Self-reported Sexual Anxiety and Arousal: The Expanded Sexual Arousability Inventory," *J. Sex. Research* 20:241-254 (1984)). Each activity was rated for its ability to arouse or to inhibit arousal. Participants were asked if particular activities were either very arousing (5) or adversely affected their arousal (-1). The twenty eight questions used to
15 assess sexual behaviors were used to rate sexual anxiety. The participants were asked to rate not only what aroused them (or turned them off) but also what activities would induced feelings of anxiety -- defined as extreme uneasiness or distress. The scale was reversed, meaning the -1 indicated that the activity was relaxing or calming and 5 indicated that the activity was extremely anxiety-producing. For example, circling the
20 number 2 in response to a question meant that the activity sometimes caused anxiety or was slightly anxiety-producing. The range allowed for differences not only among individual women, but for each woman, depending on the setting.

Results. The effect of odor on vaginal blood flow was calculated based on
25 changes from the average of the bloodflow measured while the subject was wearing the blank masks. Vaginal blood flow changes are shown in Tables I-V, below.

The sources of odorants in the Tables were as follows:

Baby powder = Internatl. Flavors and Fragrances, Inc. (IFF) (#3169-HS)

Banana nut bread = Aromatech (#256454)

Charcoal barbecue smoke = IFF (#2185-HS)

5 Cherry = Orchidia (# F180075)

Chocolate = Florasynth, Inc. (#A3898)

Cologne = Old Spice®

Cucumber = Aromatech (#256452)

Good N' Plenty® (licorice-based) = Aromatech (#236923)

10 Lavender = Energy Essentials

Perfume = Chanel No. 5

Pumpkin pie = Florasynth, Inc. Energy Essentials (#AG-6956)

15 Table I, below, shows the average change in vaginal blood flow of the entire group of female test subjects (n=19) when administered individual odorants and odorant mixtures.

TABLE I
AVERAGE % CHANGE IN VAGINAL BLOOD FLOW
IN TOTAL GROUP OF FEMALES

20

ODORANT	% CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT)
Good N' Plenty® + cucumber	+ 13 %
Baby powder	+ 13 %
Pumpkin pie + lavender	+ 11 %
Baby powder + chocolate	+ 4 %
Perfume	+ 0-1 %
Cologne	-1 %
Good N' Plenty®	-12 %
Charcoal barbecue smoke	- 14 %
Cherry	- 18 %

As a group, several smells impaired arousal. Those odors that had the greatest negative effect, meaning that the baseline blood flow measurement actually decreased, were cherry (18-percent reduction) and charcoal barbecue smoke (14-percent reduction).

Other odors had a lesser effect. Male colognes decreased vaginal flow by 1 percent, and female perfumes increased it by 1 percent. A combination of baby powder and chocolate resulted in a 4-percent increase.

Pumpkin pie and lavender increased vaginal blood flow by 11 percent. The odor that had the greatest effect to induce female sexual arousal was a combination of Good & Plenty® licorice-based odorant and cucumber which increased blood flow by 13 percent.

While the Good & Plenty® licorice-based odorant and cucumber combination was arousing to most women, difference occurred among the participants based on the kinds of sexual behavior and activities preferred. For example, the women could be subgrouped into those who found masturbation arousing and those who did not. **Table II**, below, shows the average change in vaginal blood flow of the subgroup of female individuals who indicated a high sexual arousal with masturbation on the questionnaire. **Table III**, below, shows the average change in vaginal blood flow of the subgroup of female individuals who indicated repulsion or low arousal with masturbation on the questionnaire.

TABLE II
FEMALES WITH HIGH AROUSAL WITH MASTURBATION

5 ODORANT	% CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT)
Good & Plenty® + banana nut bread	+ 28 %
Good & Plenty® + cucumber	+ 22 %
Perfume	+ 18 %

TABLE III
FEMALES WITH INHIBITION OR LOW AROUSAL WITH MASTURBATION

10 ODORANT	% CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT)
Baby powder	+ 16 %
Pumpkin pie + lavender	+ 10 %
Good & Plenty®	- 20 %

15 Among women who reported being extremely aroused by masturbation, every odor tested had an arousing effect. A Good & Plenty® licorice-based odorant and banana-nut bread combination (28-percent increase) and the Good & Plenty® licorice-based odorant and cucumber combination (22 percent) showed the greatest effect. Popular perfumes showed an 18-percent increase in vaginal blood flow, as did baby powder, which was nearly as arousing at a 16-percent increase.

20 Women who did not find masturbation extremely arousing showed an increase in vaginal blood flow of 16 percent in response to baby powder and a 1-percent response to lavender and pumpkin pie.

The women could also be subgrouped into those who were extremely aroused when a lover manually stimulated here genitals and those who were not. Table IV,

below, shows the average percent change in vaginal blood flow of the subgroup of female individuals who indicated that they are positively aroused sexually by partner's finger manipulation of the genitals on the questionnaire. Table V, below, shows the average percent change in vaginal blood flow of the subgroup of female individuals who indicated a low to zero to negative level of arousal by partner's finger manipulation of the genitals on the questionnaire.

TABLE IV
FEMALES WHO ARE POSITIVELY AROUSED
BY GENITAL FINGER MANIPULATION BY PARTNER

ODORANT	% CHANGE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT)
Good N' Plenty® + cucumber	+ 18 %
Pumpkin pie + lavender	+ 12 %

TABLE V
FEMALES WHO ARE NEGATIVELY AROUSED
BY GENITAL FINGER MANIPULATION BY PARTNER

ODORANT	% INCREASE IN VAGINAL BLOOD FLOW (OVER BASELINE MEASUREMENT)
Perfume	- 14 %
Cologne	- 14 %
Good N' Plenty® + cucumber	- 13 %

Women who found manual genital stimulation arousing showed a 12-percent increase in vaginal blood flow in response to pumpkin pie and lavender, and averaged an 18-percent increase with the Good & Plenty® licorice-based odorant and cucumber combination.

Individual odorants and odorant mixtures that increased vaginal blood flow by about 10-30%, included a baby powder odorant, a mixture of a licorice-based odorant and banana nut bread odorant, a mixture of a licorice-based odorant and cucumber odorant, a floral-aldehydic perfume fragrance (e.g., Chanel No. 5), a mixture of lavender and pumpkin pie odorants, and a mixture of baby powder and chocolate odorants. These individual odorants and odorant mixtures were particularly effective in increasing vaginal blood flow in those female individuals who are positively sexually aroused with masturbation or by manual manipulation of the genitals.

Odorants can also be administered to decrease vaginal blood flow of a female individual and the level of sexual arousal. The odorants and odorant mixtures that caused a decrease in vaginal blood flow by about 10-20% included a licorice-based odorant alone, a mixture of a licorice-based odorant and cucumber odorant, a charcoal barbecue meat odorant, a cherry odorant, a men's cologne (e.g., Old Spice), and a floral-aldehydic perfume fragrance (e.g., Chanel No. 5). These odorants and odorant mixtures were particularly effective in reducing vaginal blood flow in those female individuals who were not sexually aroused with masturbation or by touching or manipulation of the genitals by a partner.

Although not intended to limit the invention to a particular theory, one way that the odorants can act on female sexual arousal is through a learned conditioned response. If the odor is one that the female associates with a past experience of being sexually aroused, the odor may induce a sexually arousing mechanism. This could be a primary conditioned response or through secondary effects, for example, by inducing a more positive mood state or relaxed state which may cause females to remove or reduce inhibitions. Positive moods and relaxed states can be achieved either directly through a conditioned response through a learned response paradigm, or through a phenomenon of olfactory evoked nostalgia whereby an odor induces a positive mood state in an individual as a result of recalling the past.

The odorants may also act to enhance female sexual arousal by acting directly on areas of the brain in a more physiological way. For example, the odors may have

stimulated the reticular activating system of the brain which makes one awake and alert. In this alert state, the women may have become more aware of sensory stimuli in the environment, including sexual cues.

In addition, the odors may have acted directly on the brain to reduce anxiety.

5 For example, in one study, people were placed in a coffinlike tube which induced a claustrophobic response. Odors were then added to the environment and their effect was evaluated. The odor of cucumber reduced anxiety and altered participant's perception of space. In a similar way, the odor of cucumber may have reduced anxiety among the women test subjects.

10 The odorants may also impact upon sexual arousal by inducing a state of risk taking or of generalized pleasure seeking as in seeking food or other pleasure-oriented responses. In addition, the odorants may inhibit associated cortical functioning that would induce a release of the "id" or the underlying limbic system functioning, hence allowing more primitive responses. This has been observed in decorticate animals
15 (e.g., Kluver-Bucy syndrome) and in humans who have developed marked cortical deficits, such as obese Down's syndrome individuals. Similar responses have been observed in individuals who became more tired, and thus become more easily induced to sexual arousal or eating. Similarly, cortical suppression with alcohol can lead to a lack of discrimination for sexual partners, which may be due to alcohol-induced
20 inhibition of olfactory reception, similar indiscriminate mating as seen in rats.

For women for whom masturbation is extremely arousing, there are two theories about their response. In the study, a monitoring device was in place in the vagina throughout the test. The odors may have acted to change the women's focus of attention and enhanced the perception of touch. The presence or absence of one
25 sensory modality can affect our perception of another. Many people say that they have improved perception of auditory stimuli when they are in total darkness. In the study, the sense of smell may have acted on the tactile sensations produced by the vaginal monitor. Further, since these women were easily sexually excited by touch, the odors may have had an even greater effect in combination with the tactile sensation produced

by the monitoring device; their touch receptors were already conditioned to be more sensitive to tactile stimuli, and the olfactory stimulation further enhanced the perception of touch.

Alternatively, rather than odors increasing awareness of the vaginal monitoring device, the odors may have made the women less aware of the device. For some women, the monitor may have been slightly painful and the odors may have distracted them and, therefore, decreased their discomfort. Or, the odors may have acted physiologically to reduce pain. In a study of individuals who suffered from migraine headaches, the odor of green apple was shown to relieve pain; since pain inhibits sexual arousal, the odors may have acted to reduce the discomfort of the vaginal monitoring device. When there is minimal pain and discomfort, sexual arousal is enhanced.

One explanation for both the positive and negative responses that make anatomic sense is that the odors acted on the septal nucleus which is the erection center of the brain. Animal studies have shown that stimulation of the septal nucleus of the squirrel monkey results in erection, and a direct anatomic connection exists between the olfactory bulb and the septal nucleus. The odors may have acted directly on the septal nucleus to either stimulate or inhibit arousal.

The invention has been described by reference to detailed examples and methodologies. These examples are not meant to limit the scope of the invention. It should be understood that variations and modifications may be made while remaining within the spirit and scope of the invention. The disclosures of the cited references are incorporated by reference herein.

Variable	Mean	SD	Min	Max	Skewness	Kurtosis	Normality
Age	38.5	12.5	25	65	0.1	3.2	0.95
Gender	1.2	0.4	1	2	0.0	3.0	0.98
Education	15.2	2.1	12	18	0.2	3.5	0.92
Income	4500	1500	2000	8000	0.3	3.8	0.88
Health	2.5	0.8	1	4	0.1	3.1	0.96
Stress	3.2	1.1	1	5	0.2	3.4	0.94
Life Satisfaction	4.1	0.9	3	5	0.1	3.2	0.95
Work Satisfaction	3.8	1.0	2	5	0.2	3.5	0.93
Family Satisfaction	4.3	0.8	3	5	0.1	3.1	0.96
Community Satisfaction	3.9	1.1	2	5	0.2	3.6	0.92
Overall Satisfaction	4.0	0.9	3	5	0.1	3.2	0.95

- 20

8. The method of claim 6, wherein the odorant is selected from the group consisting of a licorice-based odorant, a charcoal barbecue smoke odorant, and a cherry odorant.
9. The method of claim 1, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.
10. The method of claim 9, wherein the concentration of the odorant is at about 25-55 decismel units.
11. The method of claim 1, further comprising: having the female individual inhale the odorant for about 1-3 minutes.
12. A method of screening an odorant for altering vaginal blood flow of a female individual, comprising:
administering to the female individual an odorant by inhalation in an amount and for a time period effective to alter vaginal blood flow; and
at least one of: measuring the vaginal blood flow of the female individual before and after administering the odorant; and questioning the female individual as to the effectiveness of the odorant in increasing or decreasing sexual arousal before and after inhaling the odorant substance.
13. The method of screening of claim 12, further comprising, prior to administering the odorant: testing the female individual for olfactory ability.

14. An article of manufacture, comprising, packaged together:
an odorant as recited in claim 1 packaged within a container, wherein the odorant when inhaled by a female individual is effective to alter vaginal blood flow;
and
instructions for use of the odorant for altering vaginal blood flow according to the method of claim 1.
15. The article of manufacture according to claim 14, further comprising at least one of the following:
a device for measuring vaginal blood flow of the female individual; and
means for testing olfactory ability in the female individual.
16. The article of manufacture of claim 14, wherein the concentration of the odorant is effective to provide a suprathreshold but not irritant amount of the odorant.
17. The article of manufacture of claim 16, wherein the concentration of the odorant is at about 25-55 decismel units.
18. The article of manufacture of claim 14, wherein the odorant is packaged within a delivery means selected from the group consisting of a vial, jar, pouch, can, bottle, blister pack, and a scratch-and-sniff odor patch containing microcapsules of the odorant.
19. The article of manufacture of claim 14, wherein the odorant is in a form selected from the group consisting of a cloth scented with the odorant, an aerosol spray, a pump-type spray, a nasal spray, a liquid or solid form of the odorant contained in a vessel having a cap, a liquid or solid form of the odorant contained in a blister pack, and microcapsules of the odorant contained in a scratch-and-sniff odor patch.

ABSTRACT OF THE DISCLOSURE

A non-invasive method of altering vaginal blood flow in a female individual to augment or lessen sexual arousal is provided. The method involves administering an individual odorant or odorant mixture for inhalation that is sufficient to alter vaginal blood flow of the female by about -20% to about +30% compared to a baseline vaginal blood flow without inhalation of the odorant. Also provided is a method for screening an odorant for its capacity to increase or decrease vaginal blood flow, and an article of manufacture, or kit, containing an odorant and instructions for its use in altering vaginal blood flow.

10

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By:	<u>Kristine M Strodthoff</u>
Name: Kristine M. Strodthoff	

MW2-159387-1

**United States Patent Application
COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: USE OF ODORANTS TO ALTER VAGINAL BLOOD FLOW, AND ARTICLE OF MANUFACTURE THEREFOR

the specification of which:

(a) ☐ is attached hereto.

(b) ☒ was filed on December 14, 1998 as Serial No. 09/211,507 for which I solicit a United States patent.

ACKNOWLEDGMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in 37 Code of Federal Regulations § 1.56, and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent (see last page attached hereto).

PRIORITY CLAIM (35 U.S.C. § 119)

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed, or a provisional application filed under § 111(b) of Title 35 (35 U.S.C. § 119(b)).

☐ no such applications have been filed.

☒ such applications have been filed as follows.

FOREIGN/PCT or PROVISIONAL APPLICATION(S) FILED WITHIN 12 MONTHS (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION, CLAIMING PRIORITY UNDER 35 U.S.C. § 119

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 USC § 119
USA	60/069,460	15-DEC-1997	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

FOREIGN/PCT APPLICATION(S) FILED BEFORE THE PRIORITY APPLICATION(S)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE

PRIORITY CLAIM (35 U.S.C. § 120/365)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT International application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material

information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)

POWER OF ATTORNEY

I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

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DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Residence: _____
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Inventor's signature: _____ Date _____

RULE 56 (37 U.S.C. §1.56)

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office. This includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information that is material to the patentability of a canceled or withdrawn claim need not be submitted if the information is not material to the patentability of any of the remaining claims. There is no duty to submit information that is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by 37 C.F.R. §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

- (1) prior art cited in search reports of a foreign patent office in a counterpart application, and
- (2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) Each inventor named in the application;
- (2) Each attorney or agent who prepares or prosecutes the application; and
- (3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.